

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2022-0826; Airspace Docket No. 21-AEA-21]

RIN 2120-AA66

Proposed Amendment and Establishment of Area Navigation (RNAV) Routes; Northeast United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend three low altitude Area Navigation (RNAV) routes (T-routes) and establish two T-routes in support of the VHF Omnidirectional Range (VOR) Minimum Operational Network (MON) Program. The purpose is to enhance the efficiency of the National Airspace System (NAS) by transitioning from ground-based navigation aids to a satellite-based navigation system.

DATES: Comments must be received on or before August 15, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12-140, Washington, DC 20590; telephone: (800) 647-5527, or (202) 366-9826. You must identify FAA Docket No. FAA-2022-0826; Airspace Docket No. 21-AEA-21 at the beginning of your comments. You may also submit comments through the internet at <https://www.regulations.gov>.

FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at https://www.faa.gov/air_traffic/publications/. For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267-8783.

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267-8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would expand the availability of RNAV and enhance the efficiency of the NAS by transitioning from ground-based navigation aids to a satellite-based navigation system.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA-2022-0826; Airspace Docket No. 21-AEA-21) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at <https://www.regulations.gov>.

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to FAA Docket No. FAA-2022-0826; Airspace

Docket No. 21-AEA-21." The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at <https://www.regulations.gov>. Recently published rulemaking documents can also be accessed through the FAA's web page at https://www.faa.gov/air_traffic/publications/airspace_amendments/.

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Ave., College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to amend three low altitude RNAV T-routes, designated T-287, T-358, and T-608; and to establish two T-routes designated T-318, and T-

320, in the northeast United States; to support the VOR MON Program, and the transition of the NAS from ground-based navigation aids to satellite-based navigation.

T-287: T-287 extends between the DENNN, VA waypoint (WP) (located northwest of the Gordonsville, VA, (GVE) VHF Omnidirectional Range and Tactical Air Navigational System (VORTAC)) and the TOMYD, MD, WP (located northwest of the Westminster, MD, (EMI) VORTAC). The TOMYD WP would be relocated 2.8 nautical miles (NM) to the north of its current position which would change its state location from MD to PA. This action proposes to extend T-287 from the TOMYD, PA, WP to the Kennebunk, ME, (ENE) VHF Omnidirectional Range/Distance Measuring Equipment (VOR/DME). The CAARY, VA, WP and the WILMY, VA, WP would be removed from the route description because they do not denote a turn point on the route. However, those WPs will continue to be shown on aeronautical charts for air traffic control purposes. T-287 would overlay portions of VOR Federal airway V-44 from the VYSOR, MD, WP to the WNSTN, NJ, WP. It would also overlay airway V-139 from the WNSTN, NJ, WP, to the Kennebunk VOR/DME. In the description of T-287, the WNSTN, NJ, WP replaces the Sea Isle, NJ, (SIE) VORTAC. The ORCHA, NY, WP replaces the Hampton, NY, (HTO) VORTAC. The PROVI, RI, WP replaces the Providence, RI, (PVD) VOR/DME. As amended, T-287 would extend between the DENNN, VA, WP, and the Kennebunk, ME, VOR/DME.

T-358: T-358 extends between the Martinsburg, WV, (MRB) VORTAC, and the AVALO, NJ, Fix. This action proposes to extend T-358 from the AVALO Fix, to the Augusta, ME, (AUG) VOR/DME. The HOGZZ, MD, WP would be changed to the TWIRK, MD, WP per request from air traffic control (ATC). The latitude/longitude coordinates of the WP would remain unchanged. The GOLDA, MD, Fix; the BROSS, MD, Fix; and the LEEAH, NJ, Fix would be removed from the route description because they don't denote turn points on the route. The Fixes will remain on aeronautical charts for ATC purposes. T-358 would overlay portions of airway V-268 from the AVALO Fix to the Augusta VOR/DME. The "OA" abbreviation for the HAVNS WP means "Offshore Atlantic."

T-318: T-318 is a proposed new route that would extend between the Rochester, NY, (ROC) VOR/DME and

the Kennebunk, ME, (ENE) VOR/DME. T-318 would overlay airway V-34 from the Rochester VOR/DME to the ARKK, NY, WP. It would overlay airway V-167 from the ARKK WP, to the Kennebunk VOR/DME. The location abbreviation "OA" used for the CBIRD and HUBELL WPs, and the SCUPP Fix, means "Offshore Atlantic."

T-320: T-320 is a proposed new route that would extend between the GILFF, VA, WP and the Gardner, MA, (GDM) VOR/DME. T-320 would overlay portions of airway V-308 from the BILIT, MD, Fix, to the CHOPS, MD Fix, and from the WNSTN, NJ, WP to the YANCT, CT, WP.

T-608: T-608 is an existing Canadian T route that extends into U.S. airspace between the HOCKE, MI, WP, and the YANTC, CT, WP. The FAA proposes to modify the eastern end of the route by removing the segments between the Gardner, MA, (GDM) VOR/DME and the YANCT, CT, WP. Instead, the route will be realigned to proceed eastward from the Gardner VOR/DME through the BRONC, MA; LOBBY, MA; and SOSYO, MA Fixes; terminating at the REVER, MA, Fix (located 5 NM north of the Boston, MA, (BOS) VOR/DME). The proposed new T-320 (described above) would incorporate the segments between the YANCT WP, and the Gardner VOR/DME that is being proposed for removal from T-608.

In addition, the following points would be removed from the T-608 legal description because they do not denote a turn point on the route: MONCK, NY, WP; LORTH, NY, Fix; MAGEN, NY, WP; KONDO, NY, WP; WIFFY, NY, WP; STODA, NY, WP; VASTS, NY, Fix; NORSE, NY, WP; MARIA, NY, WP; WARUV, NY, WP; GRISY, MA, WP; WARIC, MA, WP; HURLY, MA, Fix; GRAYM, MA, WP; BLATT, CT, WP; MOGUL, CT, WP; and YANCT, CT, WP.

Full route descriptions of the above T routes are listed in the amendments to part 71 set forth below.

United States RNAV T-routes are published in paragraph 6011, and Canadian RNAV T-routes are published in paragraph 6023, respectively, of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The RNAV routes listed in this document would be subsequently published in FAA Order 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures" prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 14 CFR 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T-287 DENNN, VA to Kennebunk, ME (ENE) [Amended]

DENNN, VA	WP	(Lat. 38°05'06" N, long. 078°12'28" W)
KAIJE, VA	WP	(Lat. 38°44'35" N, long. 078°42'48" W)
BAMMY, WV	WP	(Lat. 39°24'33" N, long. 078°25'46" W)
REEES, PA	WP	(Lat. 39°47'52" N, long. 077°45'56" W)
TOMYD, PA	WP	(Lat. 39°43'39.02" N, long. 077°07'58.89" W)
MOYRR, MD	WP	(Lat. 39°30'03.42" N, long. 076°56'10.84" W)
DANII, MD	WP	(Lat. 39°17'46.42" N, long. 076°42'19.36" W)
VYSOR, MD	WP	(Lat. 39°02'03.86" N, long. 076°14'59.88" W)
WNSTN, NJ	WP	(Lat. 39°05'43.81" N, long. 074°48'01.20" W)
MANTA, NJ	WP	(Lat. 39°54'07.01" N, long. 073°32'31.63" W)
BEADS, NY	WP	(Lat. 40°44'04.51" N, long. 072°32'34.21" W)
ORCHA, NY	WP	(Lat. 40°54'55.46" N, long. 072°18'43.64" W)
PARCH, NY	WP	(Lat. 41°05'57.22" N, long. 072°07'14.66" W)
PROVI, RI	WP	(Lat. 41°43'25.46" N, long. 071°25'54.17" W)
INNDY, MA	WP	(Lat. 41°46'19.19" N, long. 071°05'55.93" W)
BURDY, MA	WP	(Lat. 41°57'19.14" N, long. 070°57'07.45" W)
HAVNS, OA	WP	(Lat. 42°17'55.00" N, long. 070°27'42.00" W)
GRGIO, MA	WP	(Lat. 42°35'09.36" N, long. 070°33'54.40" W)
LBSTA, MA	WP	(Lat. 42°48'00.00" N, long. 070°36'48.70" W)
Kennebunk, ME (ENE)	VOR/DME	(Lat. 43°25'32.42" N, long. 070°36'48.69" W)

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T-358 Martinsburg, WV (MRB) to Augusta, ME (AUG) [Amended]

Martinsburg, WV (MRB)	VORTAC	(Lat. 39°23'08.06" N, long. 077°50'54.08" W)
CPTAL, MD	WP	(Lat. 39°32'16.02" N, long. 077°41'55.65" W)
TWIRK, MD	WP	(Lat. 39°34'36.70" N, long. 077°12'44.75" W)
MOYRR, MD	WP	(Lat. 39°30'03.42" N, long. 076°56'10.84" W)
DANII, MD	WP	(Lat. 39°17'46.42" N, long. 076°42'19.36" W)
OBWON, MD	WP	(Lat. 39°11'54.69" N, long. 076°32'04.84" W)
SWANN, MD	FIX	(Lat. 39°09'05.28" N, long. 076°13'43.94" W)
Smyrna, DE (ENO)	VORTAC	(Lat. 39°13'53.93" N, long. 075°30'57.49" W)
AVALO, NJ	FIX	(Lat. 39°16'54.52" N, long. 074°30'50.75" W)
MANTA, NJ	FIX	(Lat. 39°54'07.01" N, long. 073°32'31.63" W)
BEADS, NY	FIX	(Lat. 40°44'04.51" N, long. 072°32'34.21" W)
ORCHA, NY	WP	(Lat. 40°54'55.46" N, long. 072°18'43.64" W)
Sandy Point, RI (SEY)	VOR/DME	(Lat. 41°10'02.77" N, long. 071°34'33.91" W)
BURDY, MA	FIX	(Lat. 41°57'19.14" N, long. 070°57'07.45" W)
HAVNS, OA	WP	(Lat. 42°17'55.00" N, long. 070°27'42.00" W)
GRGIO, MA	WP	(Lat. 42°35'09.36" N, long. 070°33'54.40" W)
LBSTA, MA	FIX	(Lat. 42°48'00.00" N, long. 070°36'48.70" W)
MESHL, ME	FIX	(Lat. 43°19'12.07" N, long. 070°09'48.03" W)
Augusta, ME (AUG)	VOR/DME	(Lat. 44°19'12.07" N, long. 069°47'47.63" W)

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T-318 Rochester, NY (ROC) to Kennebunk, ME (ENE) [New]

Rochester, NY (ROC)	VOR/DME	(Lat. 43°07'04.65" N, long. 077°40'22.06" W)
FAULT, NY	FIX	(Lat. 42°59'03.01" N, long. 077°21'47.78" W)
BEEPS, NY	FIX	(Lat. 42°49'13.26" N, long. 076°59'04.84" W)
KOLTT, NY	WP	(Lat. 42°14'21.22" N, long. 075°41'48.39" W)
ARRKK, NY	WP	(Lat. 42°03'48.52" N, long. 075°19'00.41" W)
HELON, NY	FIX	(Lat. 41°40'02.72" N, long. 074°16'49.52" W)
Kingston, NY (IGN)	VOR/DME	(Lat. 41°39'55.62" N, long. 073°49'20.01" W)
MOONI, CT	FIX	(Lat. 41°37'53.28" N, long. 073°19'19.43" W)
Hartford, CT (HFD)	VOR/DME	(Lat. 41°38'27.98" N, long. 072°32'50.70" W)
PROVI, RI	WP	(Lat. 41°43'25.46" N, long. 071°25'54.17" W)
PEAKE, MA	FIX	(Lat. 41°34'14.87" N, long. 070°24'31.61" W)
Marconi, MA (LFV)	VOR/DME	(Lat. 42°01'01.88" N, long. 070°02'14.04" W)
CBIRD, OA	WP	(Lat. 42°08'48.41" N, long. 070°04'46.69" W)
HUBEL, OA	WP	(Lat. 42°16'34.88" N, long. 070°07'19.97" W)
SCUPP, OA	FIX	(Lat. 42°36'11.01" N, long. 070°13'49.35" W)
Kennebunk, ME (ENE)	VOR/DME	(Lat. 43°25'32.42" N, long. 070°36'48.69" W)

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T-320 GILFF, VA to Gardner, MA (GDM) [New]

GILFF, VA	WP	(Lat. 38°21'44.86" N, long. 077°26'05.38" W)
HIGPO, VA	WP	(Lat. 38°22'16.09" N, long. 077°22'19.97" W)
CAVDI, MD	WP	(Lat. 38°25'33.43" N, long. 076°54'43.49" W)
DAILY, MD	FIX	(Lat. 38°33'37.83" N, long. 076°43'31.05" W)
VAALI, MD	WP	(Lat. 38°44'00.85" N, long. 076°26'38.26" W)
BILIT, MD	FIX	(Lat. 38°45'15.82" N, long. 076°03'57.59" W)
CHOPS, MD	FIX	(Lat. 38°45'41.81" N, long. 075°57'36.18" W)
EGGRS, DE	WP	(Lat. 38°53'30.52" N, long. 075°30'49.95" W)
JILLI, NJ	WP	(Lat. 39°00'42.22" N, long. 075°05'46.21" W)
WNSTN, NJ	WP	(Lat. 39°05'43.81" N, long. 074°48'01.20" W)
MANTA, NJ	FIX	(Lat. 39°54'07.01" N, long. 073°32'31.63" W)
BEADS, NY	FIX	(Lat. 40°44'04.51" N, long. 072°32'34.21" W)
ORCHA, NY	WP	(Lat. 40°54'55.46" N, long. 072°18'43.64" W)
BOROS, NY	FIX	(Lat. 41°09'24.45" N, long. 072°09'50.96" W)
Groton, CT (GON)	VOR/DME	(Lat. 41°19'49.45" N, long. 072°03'07.14" W)
YANTC, CT	WP	(Lat. 41°33'22.81" N, long. 071°59'56.95" W)
Gardner, MA (GDM)	VOR/DME	(Lat. 42°32'45.31" N, long. 072°03'29.48" W)

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Paragraph 6013 Canadian Area Navigation Routes.

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T-608 HOCKE, MI to REVER, MA [Amended]

HOCKE, MI	WP	(Lat. 43°15'43.38" N, long. 082°42'38.27" W)
KATNO, Canada	WP	(Lat. 43°10'34.00" N, long. 082°19'32.00" W)
UKNIX, NY	WP	(Lat. 42°56'44.51" N, long. 078°55'05.60" W)
WOZEE, NY	WP	(Lat. 42°56'01.65" N, long. 078°44'19.64" W)
CLUNG, NY	WP	(Lat. 43°03'17.17" N, long. 078°00'13.38" W)
Rochester, NY (ROC)	VOR/DME	(Lat. 43°07'04.65" N, long. 077°40'22.06" W)
Syracuse, NY (SYR)	VORTAC	(Lat. 43°09'37.87" N, long. 076°12'16.41" W)
LAMMS, NY	WP	(Lat. 43°01'35.30" N, long. 075°09'51.50" W)
Albany, NY (ALB)	VORTAC	(Lat. 42°44'50.20" N, long. 073°48'11.47" W)
GRAVE, NY	WP	(Lat. 42°46'47.34" N, long. 073°22'20.91" W)
Gardner, MA (GDM)	VOR/DME	(Lat. 42°32'45.31" N, long. 072°03'29.48" W)
BRONC, MA	FIX	(Lat. 42°30'53.93" N, long. 071°43'21.61" W)
LOBBY, MA	FIX	(Lat. 42°30'15.53" N, long. 071°36'34.04" W)
SOSYO, MA	FIX	(Lat. 42°29'14.45" N, long. 071°25'55.75" W)
REVER, MA	FIX	(Lat. 42°26'27.48" N, long. 070°57'41.31" W)

Excluding the airspace within Canada.

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Issued in Washington, DC, on July 7, 2022.

Scott M. Rosenbloom,*Manager, Airspace Rules and Regulations.*

[FR Doc. 2022-14890 Filed 7-14-22; 8:45 am]

BILLING CODE 4910-13-P**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 2****[Docket No. FDA-2020-N-1383]****Revocation of Methods of Analysis Regulation****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is proposing to revoke the Methods of analysis regulation describing an FDA policy to use certain methods of analysis for FDA enforcement programs when the method of analysis is not prescribed in a regulation. FDA is proposing this action because the existing regulation is unnecessary.

DATES: Either electronic or written comments on the proposed rule must be submitted by September 28, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 28, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-

2020-N-1383 for "Revocation of Methods of Analysis Regulation." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the